

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

40226

CHEMISTRY REVIEW(S)

APPROVAL PACKAGE SUMMARY FOR 40-226

ANDA #: 40-226

FIRM: Vintage Pharmaceuticals, Inc.

DRUG: Perphenazine

DOSAGE: Tablets

STRENGTH: 2 mg, 4 mg, 8 mg, 16 mg

CGMP STATEMENT/EIR UPDATE STATUS: EER is acceptable 12/10/98

BIO STUDY/BIOEQUIVALENCE STATUS: Bioequivalence is acceptable 1/27/98

METHODS VALIDATION: The drug product is compendial-method validation is acceptable 5/20/97

STABILITY: The firm has submitted 4 ½ months satisfactory accelerated stability data at 40°C/75%RH and 24 months room temperature at 25-30°C and ambient humidity for 2 mg, 4 mg, 8 mg and 16 mg tablets in 100's and 1000's packaging sizes.

LABELING REVIEW STATUS: Labeling is satisfactory 12/14/98

STERILIZATION VALIDATION: N/A

BATCH SIZES: The firm has provided the master formula and manufacturing procedures for maximum production batches of tablets for each of 2 mg, 4 mg, 8 mg, and 16 mg.
The firm has submitted copies of the executed batch records of tablets for each of 2 mg, 4 mg, 8 mg, and 16 mg.
The firm will be using the same drug substance manufacture DMF The DMF is satisfactory, also using the same equipment and procedures.

COMMENTS: The Application is Approvable.

Reviewer: *[Signature]* Nashed E. Nashed, Ph.D.

12/29/98
Date: 12/15/98

Supervisor: *[Signature]* Paul Schwartz, Ph.D.

12/28/98
Date: 12/28/98

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1. CHEMISTRY REVIEW NO. 3 Addendum

2. ANDA # 40-226

3. NAME AND ADDRESS OF APPLICANT

Vintage Pharmaceuticals, Inc.
3241 Woodpark Blvd.
Charlotte, NC 28206

4. LEGAL BASIS FOR SUBMISSION

The firm certifies that to the best of their knowledge there is any patent claiming Perphenazine Tablets, USP either has not been filed, or has expired prior to the filing of this application, and that FDA has not granted marketing exclusivity.

5. SUPPLEMENT(s)

N/A

6. PROPRIETARY NAME

N/A

7. NONPROPRIETARY NAME

Perphenazine

8. SUPPLEMENT(s) PROVIDE(s) FOR:

N/A

9. AMENDMENTS AND OTHER DATES:

Original 12/6/96

Amendment 8/7/97

Amendment 12/23/97

Amendment 1/22/98

Amendment 12/9/98

Amendment 12/21/98

Amendment 12/22/98

Amendment 12/30/98

Comment: The 12/22/98 amendment was added by the document room before I reviewed it. However, Dr Patel returned the jacket to the Branch because the amendment dated 12/22/98 provide conflicting information. The applicant was notified by the Acting TL (Dr ya) to correct their 12/22/98 amendment. The applicant submitted an amendment on 12/30/98, which is satisfactory.

Conclusion: Approval recommended for CMC section.

Reviewer: Nashed E. Nashed, Ph.D.

Supervisor: Paul Schwartz, Ph.D.

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1. CHEMISTRY REVIEW NO. 3

2. ANDA # 40-226

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Vintage Pharmaceuticals, Inc.
3241 Woodpark Blvd.
Charlotte, NC 28206

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Amendment 12/23/97
Amendment 1/22/98
Amendment 12/9/98
Amendment 12/21/98
Amendment 12/22/98

10. PHARMACOLOGICAL CATEGORY

Management of psychotic disorders

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM

Tablets

14. POTENCY

2, 4, 8, 16 mg

15. CHEMICAL NAME AND STRUCTURE

(4-[3-(2-chlorophenothiazin-10-YL)propyl]-1-piperazineethanol)

16. RECORDS AND REPORTS

17. COMMENTS

18. CONCLUSIONS AND RECOMMENDATIONS

The application is approvable

19. REVIEWER: DATE COMPLETED:

Nashed E. Nashed, Ph.D.

12/28/98

Supervisor: Paul Schwartz, Ph.D.

12/28/98

cc: ANDA 40-226
Division File
Field Copy

Endorsements:

HFD-627/N.Nashed, Ph.D./12-28-98

HFD-627/P.Schwartz, Ph.D./12-28-98

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F/T by: bc/12-29-98